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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ZAREK, PAUL E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,922	Applicant(s) MORI ET AL.	
	Examiner Paul Zarek	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. Acknowledgement is made of Applicant's After-Final reply received on 07/02/2009.

Status of the Claims

3. Claims 1-3, 5, and 7-14 are currently pending. This is the third Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

4. Claims 1-3, and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hattori (US Patent No. 6,268,395, provided in IDS). Claims 7-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hattori (above) as applied to Claims 1 and in further view of Raffanti and Haas (Goodman & Gilman's The Pharmaceutical Basis of Therapeutics, 2001). Applicants traversed this rejection on the grounds that Hattori does not teach or fairly suggest an antiviral preparation comprising a phorbol derivative of formula I wherein R₁ is $-(CH_2)_aX(CH_2)_bCH_3$, $-(CH_2)_cX(CH_2)_dYCH_3$, or $-(CH_2)_tCH_3$. Specifically, Applicants assert that Examiner has not established that it would be obvious to replace the ester at R₁, as disclosed in Hattori, with an ether or alkyl group. Examiner finds Applicants' arguments persuasive and the rejections of Claims 1-3 and 5 over Hattori and Claims 7-14 over Hattori and Raffanti and Haas are withdrawn.

Below are listed new grounds of rejection that are not necessitated by amendment to the claims. Therefore, this office action is considered non-final.

Claim Objections

5. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

6. The text of Title 35, U.S.C. § 102(b) can be found in a prior Office action.

7. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kinzel, et al. (Cancer Research, 1979, provided in IDS).

8. Claim 1 of the instant application is drawn to a composition of formula I wherein R_1 can be is $-(CH_2)_aX(CH_2)_bCH_3$, $-(CH_2)_cX(CH_2)_dYCH_3$, or $-(CH_2)_fCH_3$. Claim 5 limits R_1 to $-(CH_2)_fCH_3$.

9. Kinzel, et al., disclose the composition comprising 12-O-ethylphorbol-13-tetradecanoate. This compound contains the same phorbol core wherein R_1 is $-(CH_2)_fCH_3$ wherein f is 1, R_2 is $-CO(CH_2)_nCH_3$ wherein n is 12, and R_3 , R_4 , and R_5 are $-H$ (Table 1). Given that Kinzel, et al., disclose an embodiment of Claim 1, a specific safety index (CC_{50}/EC_{50}) of 10 or more is considered an inherent property of the compound and composition. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for

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the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). (MPEP § 2112(I)) Therefore, Kinzel, et al., anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

10. The text of Title 35, U.S.C. § 103(a) can be found in a prior Office action.
11. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinzel, et al. (above), as applied to claims 1 and 5 above, and further in view of Hattori (above) and Raffanti and Haas (above).
12. Claim 7 of the instant application is drawn to an anti-HIV virus preparation comprising a phorbol derivative of formula 1 and at least one other agent having an anti-HIV effect. Claims 8-14 limit the other anti-HIV agent.
13. Kinzel, et al., was described above. Briefly, Kinzel, et al., disclose an embodiment of a composition of formula I. Kinzel, et al., do not demonstrate that the composition disclosed therein is an effective anti-HIV agent or a composition combined with a second anti-HIV agent.
14. Hattori teaches a phorbol-derivative compound that has anti-HIV activity that is similar to derivatives claimed in Claim 1 (compound 6). One of ordinary skill in the art would reasonably expect the phorbol derivative of Kinzel, et al., to be effective against HIV infection due to the similarity between the compounds disclosed in Kinzel, et al., and Hattori. Hattori does

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not teach a composition in which the phorbol derivative is combined with a second anti-HIV agent.

15. Raffanti and Haas teach that "[a] central principle of therapy is to inhibit viral replication as completely and durably as possible This requires administering multiple drugs simultaneously" (pg 1351, col 1, "General Principles of Antiretroviral Therapy). Anti-HIV drugs are well known in the art, including nucleoside reverse transcriptase inhibitors (NRTIs, i.e. Zidovudine), non-nucleoside reverse transcriptase inhibitors (NNRTIs, i.e. Nevirapine), and protease inhibitors (PIs, i.e. Saquinavir). Raffanti and Haas also teach the various sites of inhibiting HIV (Fig 51-1). Further, it is obvious to combine two drugs that are known to have the same effect, in this case, treating HIV infection. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.' *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)" Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine compound 6, which is taught by Hattori, with other drugs that are known to inhibit various aspects of HIV infection.

16. Claims 2 and 3 are free of the prior art.

Conclusion

17. Claims 1, 5, and 7-14 are rejected. Claims 2 and 3 are objected to.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1617